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Chise Mukaidani

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WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
WASHINGTON, DC 20006-1021

EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT

PAPER NUMBER

1632

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/509,032

Applicant(s)

MUKAIDANI ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-21 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) 3-6,12-15,19-21 and 23-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-10 and 16-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/17/2007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Status of Claims***

1. Claims 1, 3-10, 12-21, and 23-33 are pending. Claims 1, 8, 10, 16-18, and 24 are amended and claims 2 and 11 are canceled by the amendment, filed 5/17/2007.

***Election/Restrictions***

2. Claims 3-6, 12-15, 19-21, and 23-33 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/16/2006.

Claims 1, 7-10, and 16-18 are under consideration.

***Information Disclosure Statement***

3. The information disclosure statement filed 5/17/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The examiner was able to retrieve and consider the U.S. patents and WO documents listed, but copies of the non-patent literature documents could not be located.

Applicant did not provide non-patent literature reference of the IDS. Therefore it was not considered.

Applicant provided evidence in the form of a receipt that 8 references for the IDS submitted 4/22/2005 was received by the USPTO. However, none of these received references were the references disclosed on the IDS submitted 4/22/2005 and filed 5/17/2007. Therefore, the non-patent literature references submitted in this IDS were not considered.

### ***Priority***

4. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Although priority papers have been submitted in the instant case, a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. Therefore, the effective filing date is 3/25/2003, the teachings of Dandri et al. (April 2001) are applicable against the instant claims (see following rejections under 35 USC 102(b)).

### ***Claim Objections***

5. The objection of claims 1 and 10 because of the following informalities: Claims 1 and 10 recite "a liver of an immunodeficient hepatopathy mouse" on line 2 of claim 1 and lines 3 and 4 of claim 16, have been corrected to recite "the liver". Therefore, this objection is withdrawn.

The objection of claim 10 because of the following informalities: Lines 12-14 of the claim recite, "wherein the mouse transplanted with the human hepatocytes is fed

under such a condition as being protected from the attack by human complement produced by the human hepatocytes transplanted therein', has been removed from the claims. Therefore, the objection is withdrawn.

Claims 7 and 16 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims require that the method use proliferative human hepatocytes. The specification teaches that a "proliferative human hepatocyte" has the ability to proliferate in vitro (p. 19, line 16-26), which suggests that they have the ability to proliferate before transplantation. Therefore, the instant method of proliferating human hepatocytes would inherently use human hepatocytes that are proliferative. Therefore these claims do not further limit the parent claims.

Applicant traversed this objection on the grounds that it is not required by the method to determine if the human hepatocytes are proliferative prior to transplantation and therefore it is unknown if the human hepatocytes are proliferative. Therefore, the limitation specifying that the cells that hepatocytes be "proliferative human hepatocytes" further limit the claim.

Applicant's arguments have been fully considered by are not found persuasive because if the methods produced human hepatocytes that are proliferating or have proliferated in the mouse, these hepatocytes would be considered "proliferative human

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hepatocytes' regardless of whether they have been verified to be proliferative before transplantation or not. Therefore, the objection is maintained.

The objection of claims 8 and 17 are objected to for their recitation of 'hepatocytes which proliferate with colony', has been clarified. Therefore, the objection is withdrawn.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Written Description***

6. The rejection of claim(s) 1-2, 7-11, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for feeding anything under conditions as being protected from the attack by human complement and administering any complement inhibitor, is withdrawn.

Applicant traversed this rejection on the grounds that "feeding anything under conditions as being protected from the attack by human complement" has been removed from the claims. Applicant also argued that complement inhibitors are known in the art and provided examples of such from Yong-Guang Yang et al and Tamura et al. These arguments and art were considered and found persuasive. Therefore the rejection is withdrawn.

***Scope of Enablement***

7. Claims 1, 7-10, and 16-18 as amended or originally filed stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of proliferating human hepatocytes comprising transplanting proliferative human hepatocytes into the liver of a uPA-Tg/SCID immunodeficient hepatopathy mouse comprising a homozygous insertion of a uPA-Tg into the genome of a homozygous SCID mouse, administering an effective amount of the complement inhibitor, Futhan, to protect against tissue damage associated with human complement produced by human hepatocytes, proliferating said human hepatocytes in the liver of said mouse, isolating human hepatocytes from the liver of said mouse transplanted with human hepatocytes, and transplanting the human hepatocytes isolated from the liver of said mouse into other uPA-Tg/SCID immunodeficient hepatopathy mice comprising a homozygous insertion of a uPA-Tg into the genome of a homozygous SCID mouse, does not reasonably provide enablement for a method comprising transplanting non-proliferative hepatocytes and does not enable transplanting proliferative human hepatocytes into the liver of an immunodeficient hepatopathy mouse or an immunodeficient hepatopathy mouse administered any complement inhibitor by any method including feeding or a progenitor mouse obtained by mating between an immunodeficient hepatopathy mouse and a decay-accelerating factor (DAF/CD55) transgenic mouse, proliferating said human hepatocytes in the liver of said mouse, isolating human hepatocytes from the liver of said mouse transplanted with proliferative human hepatocytes, and transplanting the human hepatocytes isolated from the liver of said mouse into any other

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immunodeficient hepatopathy mice, or an immunodeficient hepatopathy mice administered a complement inhibitor or progenitor mice obtained by mating between an immunodeficient hepatopathy mice and a decay-accelerating factor (DAF/CD55) transgenic mice. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use/make the invention commensurate in scope with these claims.

Applicant traversed this rejection on several grounds. First Applicant asserts that "immunodeficient hepatopathy mouse" should not be limited to the "uPA-Tg/SCID mouse" because immunodeficient hepatopathy mice are available as a progenitor mouse by mating between a genetically immunodeficient mouse and a genetically hepatopathy mouse. Such mice are well know in the art, and a skilled artisan can practice the present invention by using known immunodeficient mice and known hepatopathy mice. Applicant also provides the art of Spanopoulou et al, Shinkai et al., Ito et al, Shults et al, Hioki et al, and Mosier et al to demonstrate that immunodeficient mice and hepatopathy mice are known in the art.

Applicant's argument and the art provided have been fully considered and are not found persuasive. It is acknowledged that immunodeficient mice and hepatopathy mice as well as immunodeficient hepatopathy mice are known in the art. However, as previously disclosed in the Office Action, mailed 11/17/2006, the use of the mouse models to proliferate human hepatocytes in the liver of said mice is highly unpredictable in the art. Pages 11-12 of the Office Action mailed, 11/17/2006 state, "However, the art teaches that the development of mouse models comprising a chimeric liver that will



support transplantation of human liver cells, let alone proliferation as is required by the instant methods is challenging and unpredictable. Kneteman et al (US 6,509,514, p.d.-1/21/2003) reports that the development of mice having chimeric livers with human hepatocytes has proven to be no simple matter and the field of xenogeneic liver transplantation has moved very slowly and met with many obstacles (col 2, lines 29-35). Pietschmann and Bartenschlager (Clin Liver Dis 7(1):23-43, 2003) report that one of the challenges is that the hepatopathy mouse models commonly used, such as the homozygous Alb-uPA transgenic mouse or crosses with this mouse, are difficult to use for the production of chimeric mouse with livers containing human hepatocytes, because of the toxicity and side effects of the transgene (see abstract). Kneteman et al also disclose that the phenotype of this transgenic mouse results in a profoundly hypofibrinogenemic state and accelerated hepatocyte death (col 240-43) and therefore timing of transplantation of these mice with human hepatocytes is critical for the repopulation and rescue them from death. Furthermore, Pietschmann and Bartenschlager teach that transplantation surgery itself can be technically challenging because it must be done a few days after birth of the mouse (see abstract). Turrini et al (Transplant Proceedings 38:1181-1184, 2006) teaches the production of a Alb-uPA/SCID/Bg mouse with a chimeric liver comprising human hepatocytes, which is similar to the methods and mouse model described in the examples of the specification (see materials and methods). However, they state, "the system is still very laborious and, in our hands, resulted in very low efficiency. Even if survival 24 hours after surgery was 74%, decreasing to 64% in the following 2 weeks, only 20% of xenotransplanted

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mice exhibited some detectable level in sera and only 2% reached a significant repopulation index of more than 50%. There exist several limiting issues in this model (1) the availability of human hepatocytes, (2) the absence of pharmacological control of disease, (3) the possibility of adaptive mutations, (4) the difficulty in performing surgery in newborn animals, and (5) the requirement of immunosuppressant [p. 1183, col1].

Overall, the art at the time of filing and presently suggest that there are many obstacles to overcome in producing a immunodeficient hepatopathic mouse model comprising human hepatocytes in its liver. Again recent art suggests a low level of efficiency producing animals that at least have detectable levels of human hepatocytes maintained in its liver and an even lower percent capable of suboptimally repopulating (i.e.-proliferating) in the mouse liver. Therefore it is clear, that many obstacles and unpredictabilities exist in that art of this methodology.

The specification further demonstrates that the instant methods are challenging, unpredictable, and require very specific parameters to successfully use the instantly claimed method to proliferate human hepatocytes. As disclosed above, to keep the uPA-Tag/SCID from become moribund at the least or dead, the methods need to rely upon the administration of a complement inhibitor to protect against tissue destruction associated with human complement produced by the human hepatocytes. The specification further disclosed that some mice needed subcutaneous administration of SCID mouse serum to support the growth and maintenance of mouse body (p. 36, lines 9-12).

Therefore, **because the instant methodology disclosed in the specification and the art is unpredictable at best and artisan would not know how to successfully use a method of human hepatocyte proliferation other than the methods specifically disclosed in the examples of the specification with specifically the uPA-Tg/SCID mouse that have been demonstrated to proliferate human hepatocytes."**

Second, Applicant asserts that the claims should not be limited to a homozygous insertion of the uPA-Tg in the mouse genome because the specification teaches the use of a hemizygous gene insertion that function in the disclosed method (as seen in Example 4, pages 39-40).

Example 4 discloses the use of uPA-Tg +/-SCID mice and uPA-Tg+/+/SCID mice pretreated with retrosine to inhibit the proliferation of mouse hepatocytes before being transplanted with human hepatocytes and treated with Futan (p. 39). The specification further discloses that human albumin concentration in the blood of hemizygous uPA-Tg/SCID mice were also increased to the same level as the homozygous uPA-Tg/SCID mice (p. 40).

These results suggest that a variation of instant method is possible in both hemizygous. However, it is unclear from the disclosure how depended the hemizygous mouse method of proliferating human hepatocytes is on the presence of the retrosine that is administered in this method and not administered in the homozygous mouse method disclosed in example 1. It is clear from the disclosure, that the method can be done with uPA-Tg/SCID homozygous mice regardless of the presence or absence of

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retrosine. However, the same is not clear for the hemizygous uPA-Tg/SCID mouse. Therefore, given that lack of support that the instant method would function with the hemizygous uPA-Tg/SCID mice without the use of retrosine and given the unpredictability of the overall transplant method as discussed above, the hemizygous uPA-Tg/SCID mice are only enabled for with the administration of retrosine in conjunction with Futan.

Third, Applicant asserts that "protecting against tissue damages associated with human complement produced by human hepatocytes" should not be limited to Futhan. Applicant asserts that complement inhibitors are well known in the art and are commonly used in transplant technology.

Applicant arguments have been fully considered and are not found persuasive. As previously disclosed on pages 14 to 15 of the Office Action, mailed 11/17/2006, "Part of the novelty of this model is the use of a complement inhibitor to produce a better transplant model that will allow for proliferation of the transplanted cells. The art does not teach the added use of a complement inhibitor. Therefore, an artisan would have to look to the specification for guidance on how to use a complement inhibitor in the instant method and which inhibitor to use. The specification does teach the administration of Futhan, however, the specification does not teach a route of administration and therefore would have to rely upon methods disclosed by the art to administer Futhan, which is via intravenous administration. Therefore, an artisan would not know how to make or use the instant invention with any other complement inhibitor or means of providing a complement inhibitor, such as production of the DAF transgenic

immunodeficient hepatopathy mouse as claimed. Therefore the instant claims are only enabled to the administration of the complement inhibitor, Futhan, by means taught in the art, mainly intravenous injection." Therefore, because the art of this transplant technology is highly unpredictable, because the absence of evidence to the contrary that other complement inhibitors will work in such a method, and because the specification teaches a novel means of overcoming some of this unpredictability with the use of the uPA-Tg/SCID mouse that is administered with Futhan, the claims are only enabled for this embodiment.

Applicant did not address the issue of enablement regarding the use of non-proliferative human hepatocytes as embraced by the broadest claim and discussed on page 15 of the Office Action, mailed 11/17/2007. Therefore, this issue is still considered an issue of enablement as previously made of record.

Therefore, because the amendment to the claims and Applicant's arguments do not overcome the rejections of record, the enablement rejection is maintained.

#### ***New Matter***

8. Claims 10 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 10 recites, "feeding the mouse transplanted with the human hepatocytes no shorter than 50 days". The originally presented claim recited, "feeding the mouse transplanted with the human hepatocytes no shorter than 50 days under such conditions as being protected from attack by human complement". The amendment broadens the scope of the claim to encompass a feeding regimen for any reason that is only limited by a time (i.e.- no shorter than 50 days) as opposed to the original embodiment, which encompassed a feeding regimen to attain protection against human complement attack.

The specification as originally filed provides no implicit or explicit support for "feeding the mouse transplanted with the human hepatocytes no shorter than 50 days", which encompasses a feeding regimen for any reason that is only limited by a time. As stated above the specification as originally filed only supports feeding under such condition as to protect from attack by human complement.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3<sup>rd</sup> paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or

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terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 2, 8, 9, 11, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

Independent claims 2 and 11 have been canceled and therefore the rejection of these claims is moot and therefore withdrawn.

The rejection of independent claims 8 and 17 and their dependent claims for the infinite recitation, ".with forming colonies" has been revised and clarified. Therefore, the rejection is withdrawn.

10. Amended claims 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Amended claim 10 recites, "feeding the mouse transplanted with the human hepatocyte for not shorter than 50 days". The metes and bounds are indefinite for this recitation because it is unclear that to what the mice are supposed be feed or even if the mouse are supposed to be fed after 50 days or what happens to the mice after 50 days.

Claims 16-18 depend from claim 10.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. The rejection of claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (Hepatology 31:173-181, 2000), is withdrawn.

Applicant amended the claims to recite, "wherein the mouse is administered a complement inhibitor and is a DAF/CD55 mouse". Brown et al does not encompass these embodiments, therefore the rejection is withdrawn.



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12. The rejection of claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Dandri et al (Hepatology 33:981-988, April 2001), is withdrawn.

Applicant amended the claims to recite, "wherein the mouse is administered a complement inhibitor are is a DAF/CD55 mouse". Dandri et al does not encompass these embodiments, therefore the rejection is withdrawn.

13. The rejection of claims 1, 7, and 8 under 35 U.S.C. 102(e) as being anticipated by Kneteman et al (US 6,509,514, filed 3/17/2000) is withdrawn.

Applicant amended the claims to recite, "wherein the mouse is administered a complement inhibitor are is a DAF/CD55 mouse". Kneteman et al does not encompass these embodiments, therefore the rejection is withdrawn.

14. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

  
PETER PARAS, JR.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600